Applicant : Verlan H. VanRheenen

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In the Specification:

Please replace paragraph [0008] with the following rewritten paragraph [0008]:

The biologically active 11β-substituted free amine (I, see Chart A), 17 α-acetoxy-21methoxy-11β-(4-,N,N-dimethylaminopheny1)-19-norpregna-4,9-diene-3,20-dione, is known, see International Publication WO97/41145, see Example IX, compound 38. This compound is a tertiary amine, -N(CH3), and as the free base, is an amorphorous solid that is difficult to isolate, characterize and establish the high purity required for an API (Active Pharmaceutical Ingredient). The 11B-substituted salts (II, see Chart A), in particular the hydrochloride and hydrobromide, are stable, crystalline solids that are readily characterized, and have properties suitable for an API. The hydrochloride and hydrobromide salts are prepared by dissolving the corresponding free base 11\(\beta\)-substituted free amine (I) in suitable organic solvent including but not limited to acetone, ethyl acetate, acetonitrile, ethanol, ether, MTBE, isopropinol and mixtures thereof. The preferred solvent mixture is made up of acetone, ethyl acetate and ether. To an approximate 1 molar solution of the 11β-substituted free amine (I) in a suitable solvent at about 20-25° is added one equivalent of hydrogen chloride or hydrogen bromide either as a gas or in solution. Suitable conditions, include using the 11β-substituted free amine (I) at a concentration of about 0.1 to about 10 molar, the temperature of about 20-25°C ± 40°, and the solution of HC1 or HBr which may be in water or in a suitable organic solvent as defined above. Preferred is a 1 molar solution of the 11\beta-substituted free amine (I) in a suitable solvent at 20-25°C to which is added hydrogen chloride. The crystalline mass formed is cooled, filtered, washed with a small amount of cold solvent, and dried to constant weight under reduced pressure. This solid crystalline material may be recrystallized from a suitable solvent such as those set forth above. The preferred solvent system is ethanol/ether.

[8000]